

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re: Martin R. Willard et al. Confirmation No.: 8579
Serial No.: 10/750,586 Examiner: Christopher P. Bruenjes
Filing Date: December 29, 2003 Group Art Unit: 1772
Docket No.: 1001.1714101 Customer No.: 28075
For: CATHETER INCORPORATING AN IMPROVED POLYMER SHAFT

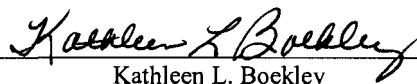
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Assistant Commissioner for Patents
P.O. Box 1450
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AMENDED APPEAL BRIEF FILED UNDER 37 C.F.R. § 41.37

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By



Kathleen L. Bockley

Dear Sirs:

Pursuant to 37 C.F.R. § 41.37, Appellants hereby submits this Amended Appeal Brief in furtherance of the Notice of Appeal filed on April 10, 2007, and of the Notice of Panel Decision from Pre-Appeal Review dated Mailed May 8, 2007. Appellants understand that the fee prescribed by 37 C.F.R. § 41.20(b)(2) in the amount of \$500.00 was charged to Deposit Account No. 50-0413 with the original appeal brief. Permission is hereby granted to charge or credit Deposit Account No. 50-0413 for any errors in fee calculation.

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I. REAL PARTY IN INTEREST

The real party in interest is the assignee of record, Boston Scientific Scimed, Inc., a corporation organized and existing under and by virtue of the laws of Minnesota, and having a business address of One SciMed Place, Maple Grove, MN 55311-1566. An assignment from the inventors, Martin R. Willard and Pu Zhou, conveying all right, title and interest in the invention to SciMed Life Systems, Inc. has been recorded at Reel 015257, Frame 0770. A Change of Name from SciMed Life Systems, Inc. to Boston Scientific Scimed, Inc. has been recorded at Reel 018505, Frame 0868.

II. RELATED APPEALS AND INTERFERENCES

There are no other known appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

Claims 26-43 are pending in the application, of which claims 26-27 are withdrawn. Claims 1-25 have been cancelled from the application.

Claims 28-43 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Itou et al. (EP 1 068 876 A2) in view of Utsumi et al. (U.S. Patent No. 5,258,160).

Claims 28-43 of the application are currently being appealed

IV. STATUS OF AMENDMENTS

No amendments were filed subsequent to the Final Office Action of January 10, 2007.

V. SUMMARY OF CLAIMED SUBJECT MATTER*

The invention relates generally to a catheter shaft having proximal, intermediate and distal portions of a specific composition. See abstract.

Independent claim 28 is directed to a catheter shaft including a polymer blend shaft (page 5, lines 7-8), comprising a proximal portion having about 80 to about 95 weight %

* The references to the specification and drawings provided herein are exemplary, and are not deemed to be limiting. For simplicity and because the application was restricted to the embodiment of Figures 2 and 3, the references to the specification and drawings are primarily directed toward Figures 2 and 3 and the corresponding description in the specification, but this is not meant to be limiting as support may be found throughout the specification and in many of the Figures.

polyoxymethylene homogeneously blended[†] with about 5 to about 20 weight % polyether polyester (page 5, lines 17-21, Figure 1 reference numeral 14); an intermediate portion coupled to the proximal portion, the intermediate portion having about 20 to about 50 weight % polyoxymethylene and about 50 to about 80 weight % polyether polyester and a uniform wall thickness (page 5, lines 22-23, Figure 1 reference numeral 18); and a distal portion coupled to the intermediate portion, the distal portion having about 5 to about 20 weight % polyoxymethylene and about 80 to about 95 weight % polyether polyester (page 5, line 23 to page 6, line 2, Figure 1, reference numeral 16).

Independent claim 29 is directed to a catheter shaft comprising: an inner layer (page 7, lines 1-3, Figure 2 reference numeral 30); a support member disposed over the inner (page 7, lines 1-3, Figure 2 reference numeral 28); and an outer layer disposed over the inner layer, the outer layer including a proximal portion having about 80 to about 95 weight % polyoxymethylene homogeneously blended with about 5 to about 20 weight % polyether polyester, an intermediate portion having about 20 to about 50 weight % polyoxymethylene and about 50 to about 80 weight % polyether polyester and having a uniform wall thickness, and a distal portion having about 5 to about 20 weight % polyoxymethylene and about 80 to about 95 weight % polyether polyester, wherein the intermediate portion is disposed between the proximal portion and the distal portion (page 7, lines 3-10, Figure 2 reference numeral 26).

Recitation of “homogeneously blended” is supported in the specification. While this phrase does not appear verbatim in the specification, support can be found on page 5, lines 7-8 and page 6, lines 14-15: “Shaft 12, or sections thereof, may be manufactured from or otherwise include a polymer blend.” “Manufacturing the polymer blended sections 14/16/18 may include extrusion of a polyoxymethylene pre-blend.”

VI. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 28-43 are unpatentable under 35 U.S.C. § 103(a) over Itou et al. (EP 1 068 876 A2) in view of Utsumi et al. (U.S. Patent No. 5,258,160).

[†]

VII. ARGUMENT

- A. Claims 28-43 are patentable under 35 U.S.C. § 103(a) over Itou et al. (EP 1 068 876 A2) in view of Utsumi et al. (U.S. Patent No. 5,258,160).

1. *Prior art references must teach or suggest all of the claimed limitations.*

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). However, independent claim 28 recites, in part “a proximal portion having about 80 to about 95 weight % homogeneously blended with about 5 to about 20 weight % polyether polyester.” Neither Itou et al. nor Utsumi et al. teach or disclose “a proximal portion having about 80 to about 95 weight % polyoxymethylene *homogeneously blended* with about 5 to about 20 weight % polyether polyester”, and therefore the combination of Itou et al. and Utsumi et al. does not establish a *prima facie* case of obviousness.

In the Final Office Action of January 10, the Examiner argues that Itou et al. disclose the homogeneous blending of two materials within the claimed weight range and that Utsumi et al. teach the use of the particular materials claimed. However, careful review of Itou et al. suggests that this does not appear to be true.

Itou et al. teach winding first and second linear members 51 and 52 around a base tube, which are then melted by heating. (Itou et al., figures 5 and 6, paragraph 80.) Itou teach that “during the heating, it is possible for the first linear member 51 and the second linear member 52 to be melted completely and to be solidified in a uniformly mixed or fused state.” (Itou et al., column 15, lines 29-32.) It is this statement which forms the basis of the incorrect assertion by the examiner that Itou et al. teach homogeneous blending.

The term “homogeneous” is used in the art to describe a state where the constituent molecules are evenly dispersed among each other. However, “uniformly mixed” does not compel homogeneity. A composition can be uniformly mixed without being homogenous. For example, concrete is a uniformly mixed composition of cement and aggregates but because discrete portions of the concrete have different compositions, concrete is classified as heterogeneous and not homogeneous.

To determine whether the resin layer of Itou et al. is homogeneously blended, therefore, one cannot rely on the phrase “solidified in a uniformly mixed or fused state.” Consequently,

one must look at the process that produces the resin layer to see whether the “uniformly mixed or fused state” described by Itou et al. is necessarily a homogeneous state.

“The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). Therefore, “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

The two materials that make up the resin layer of Itou et al. are wound around the base tube and then melted by heating. (Itou et al., column 15, lines 5-7). There is no mechanical agitation of these two separate ribbons; therefore any mixing that occurs is as a result of diffusion, surface tension effects, precipitation or other effect at the molecular level. Only the first of these effects, diffusion, is one that would tend towards producing a homogeneous mixture; the other two, surface tension effects and precipitation, would tend towards produce discrete globules of the one material within the other. Moreover, the rate of diffusion is inversely proportional to the size of the molecules. Both of the polymers claimed, polyoxymethylene and polyether polyester are molecules that can have quite large molecular weights. Therefore, even if both are fully melted, it is unlikely that the one polymer will fully diffuse into the other to produce a homogeneous resin layer. More pertinently, because large molecules such as these can have slow rates of diffusion, it is possible to fully melt these two polymers next to each other, as is done in the process of Itou et al., without fully diffusing the one into the other to produce a homogeneous layer. Because the process described by Itou et al. does not guarantee a homogeneous blend of the two polymers, a homogeneous blend of the two polymers does not necessarily flow from the process described by Itou et al.

Because disclosure by Itou et al. of “the first linear member 51 and the second linear member 52 to be melted completely and to be solidified in a uniformly mixed or fused state” does not necessarily mean that the two linear members are homogeneously blended and also because the process described by Itou et al. of melting the two linear members together does not necessarily result in a homogeneous blend of the two linear members, Itou et al. do not disclose a proximal portion have a homogeneous blend of two polymers. This is an element not disclosed

by Utsumi et al. either. Consequently no *prima facie* case of obviousness exists because the cited prior art does not teach or suggest all the claim elements.

2. *Conclusion.*

Because the combination of Itou et al. with Utsumi et al. does not teach all the limitations of the claimed invention, the Examiner has failed to establish a *prima facie* case of obviousness. As such, claims 28-43 are believed to be allowable over Itou et al. in view of Utsumi et al.

B. CONCLUSION.

For the reasons stated above, the claims 28-43 are nonobvious over Itou et al. in view of Utsumi et al., and the Examiner's rejections of these claims under 35 U.S.C. § 103(a) should be overruled.

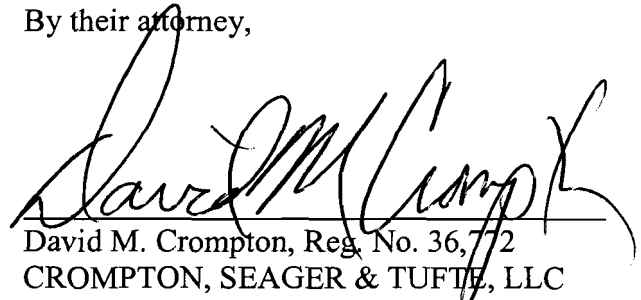
Respectfully submitted,

Martin R. Willard et al.

By their attorney,

Date: _____

8/10/07


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VIII. CLAIMS APPENDIX

28. A catheter shaft, including a polymer blend shaft, comprising:

a proximal portion having about 80 to about 95 weight % polyoxymethylene homogeneously blended with about 5 to about 20 weight % polyether polyester;

an intermediate portion coupled to the proximal portion, the intermediate portion having about 20 to about 50 weight % polyoxymethylene and about 50 to about 80 weight % polyether polyester and a uniform wall thickness; and

a distal portion coupled to the intermediate portion, the distal portion having about 5 to about 20 weight % polyoxymethylene and about 80 to about 95 weight % polyether polyester.

29. A catheter shaft, comprising:

an inner layer;

a support member disposed over the inner layer; and

an outer layer disposed over the inner layer, the outer layer including a proximal portion having about 80 to about 95 weight % polyoxymethylene homogeneously blended with about 5 to about 20 weight % polyether polyester, an intermediate portion having about 20 to about 50 weight % polyoxymethylene and about 50 to about 80 weight % polyether polyester and having a uniform wall thickness, and a distal portion having about 5 to about 20 weight % polyoxymethylene and about 80 to about 95 weight % polyether polyester, wherein the intermediate portion is disposed between the proximal portion and the distal portion.

30. The catheter shaft according to claim 29, wherein the inner layer comprises polytetrafluoroethylene.

31. The catheter shaft according to claim 29, wherein the inner layer comprises high-density polyethylene.

32. The catheter shaft according to claim 29, wherein the support member includes a braid.

33. The catheter shaft according to claim 29, wherein the support member includes a coil.

34. The catheter shaft according to claim 29, wherein the inner layer defines a guidewire lumen extending therethrough.

35. The catheter shaft according to claim 29, wherein an inflation lumen is defined between the inner layer and the outer layer.

36. The catheter shaft according to claim 29, further comprising a balloon coupled to the catheter shaft.

37. The catheter shaft according to claim 29, further comprising a distal tip coupled to and disposed distally of the inner layer, outer layer, and support member.

38. The catheter shaft according to claim 37, wherein the distal tip is comprised of polyether polyester.

39. The catheter shaft according to claim 28, further comprising an inner polytetrafluoroethylene tubular member disposed within the polymer blend shaft.

40. The catheter shaft according to claim 39, further comprising a braided metallic support member disposed between the inner polytetrafluoroethylene tubular member and the polymer blend shaft.

41. The catheter shaft according to claim 28, wherein the proximal portion, intermediate portion and distal portion define a total shaft length and the proximal portion is about 60 to about 90% of the total length, the intermediate portion is about 15 to about 20% of the total length, and the distal portion is about 2 to about 7% of the total length.

42. The catheter shaft according to claim 28, further comprising a distal tip coupled to the distal portion of the catheter shaft.

43. The catheter shaft according to claim 42, wherein the distal tip is comprised of polyether polyester.

IX. EVIDENCE APPENDIX

No additional evidence has been presented.

X. RELATED PROCEEDINGS APPENDIX

None